CONNELL FOLEY LLP
ATTORNEYS AT LAW

85 LIVINGSTON AVENUE
ROSELAND, NJ 07068-3702
(973) 535-0500
FAX: (973) 535-9217

OTHER OFFICES

HARBORSIDE FINANCIAL CENTER
2510 PLAZA FIVE
JERSEY CITY, NJ 07311
(201) 521-1000
FAX: (201) 521-0100

888 SEVENTH AVENUE
9TH FLOOR
NEW YORK, NY 10106
(212) 307-3700
FAX: (212) 262-0050

1500 MARKET STREET
12TH FLOOR,
EAST TOWER
PHILADELPHIA, PA 19102
(215) 246-3403
FAX: (215) 665-5727

LIBERTY VIEW
457 HADDONFIELD
ROAD, SUITE 230
CHERRY HILL, NJ 08002
(856) 317-7100
FAX: (856) 317-7117

THE ATRIUM, SUITE E
309 MORRIS AVENUE
SPRING LAKE, NJ 07762
(732) 449-1440
FAX: (732)449-0934

JOHN A. PINDAR (1969)
GEORGE W. CONNELL (2005)
ADRIAN M. FOLEY, JR.
GEORGE J. KENNY*
KENNETH F. KUNZMAN
SAMUEL D. LORD (2012)
RICHARD D. CATENACCI
RICHARD J. BADOLATO*
PETER D. MANAHAN
JOHN B. MURRAY
MARK L. FLEDER
KEVIN J. COAKLEY
THOMAS S. COSMA
KATHLEEN S. MURPHY
PATRICK J. MCAULEY
PETER J. PIZZI*+
KEVIN R. GARDNER
ROBERT E. RYAN
MICHAEL X. MCBRIDE*
JEFFREY W. MORYAN*
EDWARD S. WARDELL
PETER J. SMITH*
WILLIAM P. KRAUSS
BRIAN G. STELLER
PHILIP F. MCGOVERN, JR.
KAREN PAINTER RANDALL
LIZA M. WALSH
JOHN P. LACEY*
MICHAEL J. CROWLEY-
TIMOTHY E. CORRISTON*
PATRICK J. HUGHES*+
JAMES C. MCCANN*
JOHN D. CROMIE

ANGELA A. IUSO*
WILLIAM T. MCGLOIN*
BRENDAN JUDGE
STEPHEN A. URBAN
CHARLES J. HARRINGTON III+
STEPHEN V. FALANGA*
TRICIA O'REILLY*
ANTHONY F. VITIELLO*+
MARC D. HAEFNER
JONATHAN P. MCHENRY
BRAD D. SHALIT*
M. TREVOR LYONS*
CRAIG S. DEMARESKI*
W. NEVINS MCCANN*
THOMAS J. O'LEARY*
MITCHELL W. TARASCHI
MICHAEL A. SHADIACK
OWEN C. MCCARTHY*
PATRICIA A. LEE*+
AGNIESZKA ANTONIAN*
CHRISTOPHER J. TUCCI+
NEIL V. MODY*
STEVE BARNETT*
THOMAS M. SCUDERI*
JOSEPH M. MURPHY*
NANCY A. SKIDMORE*
CHRISTINE S. ORLANDO
JENNIFER C. CRITCHLEY*
PATRICK S. BRANNIGAN*
CHRISTINE I. GANNON*
ANDREW C. SAYLES*
WILLIAM D. DEVEAU*

*ALSO ADMITTED IN NEW YORK
+ALSO ADMITTED IN PENNSYLVANIA
-ONLY ADMITTED IN NEW YORK

PLEASE REPLY TO ROSELAND, NJ

COUNSEL

JOHN W. BISSELL
EUGENE J. CODEY, JR.
FRANCIS J. ORLANDO
FRANCIS E. SCHILLER*
EUGENE P. SQUEO*
BRIAN P. MORRISSEY-
NOEL D. HUMPHREYS*
ANTHONY ROMANO II*

KARIN I. SPALDING*
JODI ANNE HUDSON*
RICHARD A. JAGEN
JASON E. MARX*
ALEXIS E. LAZZARA
GAIL GOLDFARB
THOMAS VECCHIO+
DANIEL B. KESSLER*

DOUGLAS J. SHORT*
JAMES M. MERENDINO
MICHELE T. TANTALLA*
HECTOR D. RUIZ*
ROBERT A. VERDIBELLO*
PHILIP W. ALLOGRAMENTO III*
STEPHEN D. KESSLER
CHRISTOPHER ABATEMARCO*
ANTHONY J. CORINO*
INGRID E. DA COSTA
MEGHAN BARRETT BURKE*
RUKHSANAH L. SINGH*
BRITTANY E. MIANO*
STACIE L. POWERS*
NICOLE B. DORY*
MICHAEL BOJBASA-
CHRISTOPHER M. HEMRICK*
SUSAN KWIATKOWSKI*
MELISSA D. LOPEZ
ANDREW L. BARON*
JASON D. FALK*
MICHAEL J. SHORTT+
VICTORIA N. MANOUSHAGIAN*
PATRICK J. MURPHY, III*

MEGHAN K. MUSSO*
BRENDAN W. CARROLL*
ELEONORE OFOSU-ANTWI*
EDMUND J. CAULFIELD*
SYDNEY J. DARLING*
JESSICA L. PALMER*
NEIL V. SHAH*
STEPHEN R. TURANO*
STEVEN A. KROLL*
ROBERT M. DIPISA*
MATTHEW A. BAKER+
MICHAEL J. CREEGAN*
THOMAS M. BLEWITT, JR.+
BRIAN S. WOLFSON
MARY F. HURLEY
DANIELLE M. NOVAK+
KATELYN O'REILLY
JAMES E. FIGLIOZZI-
MATTHEW D. FIELDING*
MELISSA L. HIRSCH+
MARIEL L. BELANGER*
NICHOLAS W. URCIUOLI
KERRY C. DONOVAN
GENEVIEVE L. HORVATH

March 20, 2013

VIA ECF & FEDERAL EXPRESS
Hon. Susan D. Wigenton, U.S.D.J.
King Building & U.S. Courthouse
50 Walnut St., P.O. Box 999
Newark, NJ 07101-0999

Re: *Montvale Surgical Center a/s/o Thomas S. v. Aetna Ins. Co. et al.*, Civ. No. 12-2874 (SDW/MCA)

Dear Judge Wigenton:

This firm represents Aetna Health Inc. (improperly pled as "Aetna Insurance Company") (hereinafter "Aetna") in the above-referenced matter. On March 4, 2013, Plaintiff Montvale Surgical Center (hereinafter "MSC") filed its Opposition to Aetna's Motion for Summary Judgment. (Doc. No. 21). In lieu of a more formal brief, please accept this letter in reply to MSC's Opposition, and in further support of Aetna's Motion.

1. Aetna's Benefits Determination Was Not Arbitrary And Capricious

Contrary to MSC's attempts at obfuscation, resolution of Aetna's present Motion simply involves a pairing of the Plan's clear terms with the deferential and admittedly applicable standard of review under ERISA.

As Aetna noted in its Moving Brief, and MSC does not dispute, the Plan establishes certain "Non-Covered Services and Supplies and Non-Covered Charges" as follows:

> THE FOLLOWING ARE NOT COVERED SERVICES AND SUPPLIES WITH RESPECT TO NETWORK SERVICES AND SUPPLIES, AND ARE NOT COVERED CHARGES WITH RESPECT TO NON-NETWORK BENEFITS UNDER THE CONTRACT
>
> . . .
>
> **Experimental or Investigational** treatments, procedures, hospitalizations, drugs, biological products or medical devices, except as otherwise stated in the [Plan].

(Aetna R. 56.1 Stm't at ¶ 6; MSC Resp. at ¶ 6) (Doc. Nos. 18, 21). Thus, unequivocally and without more, the Plan mandates that services determined to be "experimental or investigational" are "NOT COVERED." Further, the Plan undisputedly vests Aetna with the discretion to determine what procedures are "experimental and investigational" based upon certain established criteria. (Id. at ¶¶ 3, 7-9). Accordingly, Aetna determined that Platelet Rich Plasma ("PRP") injections are "experimental and investigational" and documented both the rationale and clinical support for that determination in Clinical Policy Bulletin Number 0784: "Blood Product Injections for Selected Indications" (hereinafter "CPB 0784"). (Id. at ¶¶ 13-15). Since its original publication on May 8, 2009, CPB 0784 has been updated four times, with the most recent version taking effect just weeks ago on February 5, 2013. (Id. at 13). It is indisputable that CPB 0784, both in its original and updated versions, documents Aetna's determination that insufficient "peer-reviewed medical literature" exists to establish the efficacy, safety and appropriate use of PRP injections over current conventional treatment of musculoskeletal indications and soft tissue injuries. (See Exhibits B & C to the Certification of Michael C. McNamara) (Doc. No. 18). Despite its use by providers such as MSC, there is nonetheless a lack of high-level evidence regarding randomized clinical trials assessing the efficacy of PRP in treating ligament and tendon injuries. While MSC cites to a couple of small case studies on PRP injections, it has not, and cannot demonstrate that there have been randomized controlled clinical trials assessing the efficacy of PRP injections, with adequate and validated clinical and functional outcome measures and sound statistical analysis. Those very shortcomings align *precisely* with the criteria established by the undisputed terms of the Plan for Aetna to determine, in its discretion, that a procedure is "experimental or investigational." (See Aetna R. 56.1 Stm't at ¶¶ 7-9; MSC Resp. at ¶¶ 7-9) (Doc. Nos. 18, 21).

In its Opposition, MSC repeatedly acknowledges that the appropriate standard of review in this case is whether Aetna's benefits determination was "arbitrary and capricious." (MSC Opp'n Br. at pp. 10 - 13). Therefore, as Aetna made clear in its Moving Brief, the appropriate question in this case is not "how best to interpret the Plan," but "whether the Plan Administrator's interpretation of the Plan was reasonable." Conkright v. Frommert, 130 S. Ct. 1640, 1649 (2010). Where the claim administrator's actions were based upon the clear language of the policy, those actions were not "arbitrary or capricious" as a matter of law and the court must defer to the Claim Administrator. Shapiro v. Metro. Life Ins. Co., Civ. A. No. 08-6204, 2010 WL 1779392 (D.N.J. Apr. 30, 2010), aff'd, 430 Fed. App'x 169 (3d Cir. 2011). Furthermore, "[t]he Court may not substitute its own judgment as to the interpretation of the plan where this heightened standard is

deemed appropriate." Id. at *4-5 (citing Moats v. United Mine Workers of Am. Health & Ret. Funds, 981 F.2d 685, 687-88 (3d Cir. 1992)).

When this case is viewed through that clear lens, there is simply no genuine issue of material fact that Aetna reasonably interpreted the terms of the Plan, and applied the terms of the Plan appropriately. Indeed, the following four undisputed facts necessarily resolve this case at the summary judgment stage. First, the Plan expressly states that "experimental and investigational" services are "NOT COVERED." (Aetna R. 56.1 Stm't at ¶ 6; MSC Resp. at ¶ 6) (Doc. Nos. 18, 21). Second, the Plan vests Aetna with the discretion to determine what services are "experimental and investigational" pursuant to certain well-defined guidelines. (Id. at ¶¶ 3, 7-9). Third, Aetna published CPB 0784, and therein documents Aetna's position that PRP injections are "experimental and investigational." (Id. at ¶¶ 13-14). Lastly, Aetna cited to and relied upon CPB 0784 when it denied the claims at issue in this case, and its clinician's review on appeal expressly agreed with the application of CPB 0784 to deny the procedure at issue. (Id. at ¶ 29). Thus, it is not reasonably disputable that Aetna's actions were squarely in-line with, and were in fact mandated by, the terms of the Plan.

Not surprisingly, MSC's Opposition presents nothing to challenge that self-evident proposition other than factual inaccuracies, and citation to unexceptional or inapposite case law. Indeed, MSC's key factual contention in its Opposition -- that Aetna failed to consider two cherry-picked articles -- is simply wrong. In reality, the most recent and currently effective version of CPB 0784 not only cites the very articles in question, but discusses each of them at length. (See Exhibit C to the Certification of Michael C. McNamara) (Doc. No. 18). It is indisputable that CPB 0784 discusses the Mishra and Pavelko (2006) article, and notes that the authors "stated that further evaluation of this novel treatment [PRP injections] is warranted."[1] (Id. at pp. 4-5). Similarly, CPB 0784 discusses the Peerbooms (2010) article, and notes that the authors "stated that future decisions for application of the PRP for lateral epicondylitis should be confirmed by further follow-up from this trial and should take into account possible costs and harms as well as benefits." (Id. at p. 5). Thus, contrary to MSC's erroneous assertions, Aetna has considered the two articles in question, and explained why in view of those articles (and others), Aetna has made the discretionary determination that PRP injections are "experimental and investigational."

MSC's legal arguments in its Opposition fare no better. Indeed, the very legal standard cited by MSC makes clear that its claims are baseless. MSC cites Orvosh v. Program of Group Ins. For Salaried Employees of Volkswagen of Am. Inc., 222 F.3d 123, 129 (3d Cir. 2000), for the well-established proposition that "[a] plan administrator's decision is arbitrary and capricious if 'it is clearly not supported by the evidence in the record or the administrator has failed to comply with the procedure required by the plan.'" (MSC Opp'n Br. at p. 10) (Doc. No. 21). Aetna concurs. As noted above, it is indisputable that Aetna's benefits determination in this case was clearly supported

[1] In its Opposition, MSC conveniently omits the following highly relevant statement from its citation to the Mishra and Pavelko (2006) article: "Further evaluation of this novel treatment [Platelet Rich Plasma Injections] is warranted." As noted above, CPB 0784 recites this identical conclusion.

by the evidence in the record (i.e., CPB 0784), and fully complied with the terms of the Plan. Thus, Aetna should prevail even under MSC's recitation of the applicable law.

Further, MSC claims that the "holding" of DeVito v. Aetna, 536 F.Supp.2d 523 (D.N.J. 2008), is instructive and "urges the Court to adopt the DeVito reasoning in this case." (MSC Opp'n Br. at pp. 12 - 13). The DeVito case, however, dealt with a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), not a motion for summary judgment. Further, the underlying challenge in DeVito related to Aetna's determination that an eating disorder diagnosis was not biologically-based and, therefore, not entitled to expanded benefits pursuant to the New Jersey Mental Health Parity Law. The quoted language of the DeVito decision expressly stated that the suit turned on the requirements of the New Jersey law, and that medical necessity was *not* the focus of the suit. The unique factual and legal arguments in DeVito are completely inapplicable to the case at bar, where the suit focuses solely on whether Aetna properly determined that the PRP procedure was experimental and investigational, in accordance with the discretion afforded to Aetna and the express terms of the Plan. Therefore, the factual circumstances and procedural posture of this case and DeVito differ substantially, and MSC's tangential analogy is baseless.

Finally, in the last paragraph of its Opposition, MSC chides Aetna for failing to present a case that deals precisely with PRP injections amongst the veritable cornucopia of recent, pointed ERISA case law discussed in Aetna's Motion Brief. Yet, MSC neglects to cite any such case itself.

In sum, MSC's Opposition exhibits a fundamental misapprehension of both the undisputed and controlling terms of the Plan, and the applicable standard of review under ERISA. As such, there is no genuine issue of material fact that Aetna's benefits determination was appropriate, and Aetna's Motion should be granted.

2. ERISA Preempts MSC's State Law Claims, And Aetna Is Entitled To Reasonable Attorney's Fees And Costs

In its Opposition, MSC "concedes" that ERISA governs this case. (MSC Opp'n Br. at pp. 2-3) (Doc. No. 21). Despite that, MSC does not address or oppose Aetna's contention that the four state law causes of action lodged against Aetna in MSC's Complaint are preempted. As such, for the reasons set forth in Aetna's Moving Brief, there is no genuine issue of material fact that MSC's state law claims are preempted by ERISA.

Similarly, in its Opposition, MSC does not address or oppose Aetna's contention that the Court, in its discretion, should award Aetna its reasonable attorney's fees and costs in connection with this litigation. Indeed, MSC presents nothing in its Opposition that can be reasonably construed to assail Aetna's fundamental contention that MSC knew or should have known that its claims in this case are entirely baseless. As such, for the reasons set forth in Aetna's Moving Brief, an award of reasonable attorney's fees and costs is appropriate in this case.

3. Conclusion

For the reasons noted above, and as set forth in Aetna's Moving Brief, Aetna respectfully request that this Court grant summary judgment in its favor and dismiss MSC's Complaint with prejudice.

Respectfully submitted,

s/ Edward S. Wardell

Edward S. Wardell

cc: Andrew R. Bronsnick, Esq. (Via ECF and Email)